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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,637	02/06/2007	Dieter Scheller	6102-000034/US/NP	2828
28997	7590	05/12/2011	EXAMINER	
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7700 Bonhomme, Suite 400				
ST. LOUIS, MO 63105				
			ART UNIT	PAPER NUMBER
			1628	
			MAIL DATE	DELIVERY MODE
			05/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,637	SCHELLER ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Reopening of Prosecution After Appeal Brief

1. In view of the Appeal Brief filed on 1/28/2011, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

2. To avoid abandonment of the application, appellant must exercise one of the following two options:

(A) File a reply under 37 CFR 1.111; or

(B) Initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

3. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Status of the Claims

4. Claims 10-20, filed 6/29/2009, are currently pending. Claims 15-18 remain withdrawn. Accordingly, claims 10-14 and 19-20 are the subject of this Office Action.

Response to Arguments

5. Applicant's arguments, filed 1/28/2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. In particular, the rejection of claims 10-14 and 19-20 under 35 U.S.C. 103(a) has been withdrawn in view of Applicant's arguments. It is considered persuasive that the skilled artisan would not have

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selected a non-specific D2L/D3 dopamine receptor agonist for modification (i.e., the skilled artisan would have selected a compound which exhibits selectivity for the D3 receptor).

6. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Arguments directed to withdrawn rejections are hereby rendered moot.

Allowable Subject Matter

7. Claims 19-20 are allowable for the reasons discussed above. Namely, the claimed compounds have been searched and are deemed free of the prior art. Furthermore, it would not have been obvious to select the closest structurally related compound(s) taught by the prior art for modification since the closest structurally related compound(s) are disclosed as non-specific D2L/D3 dopamine receptor agonists and, furthermore, the prior art teaches the desire to find compounds which exhibit selectivity for the D3 receptor. As such, a person of ordinary skill in the art would not have selected a non-specific D2L/D3 dopamine receptor agonist for modification to arrive at the instantly claimed compounds.

8. Since the compounds of claims 19-20 are considered enabled and possess written support, the claims are allowed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. **Claims 10-11 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by *Swart et al* (J Analyt Toxicol 18:71-77, 1994 – cited in a previous Action) as evidenced by *Beane* (Advance Lubrication Techniques – available online at <http://contrails.iit.edu>).**

11. Instant claim 10 is drawn to a pharmaceutical composition comprising **(S)-2-N-propylamino-5-hydroxytetralin** (claim 11, more specifically, as a pure (S)-enantiomer as recited by claim 14) or a pharmaceutically acceptable salt or prodrug thereof (wherein said prodrug is a compound as defined by claim 10), and at least one pharmaceutically acceptable **carrier or adjuvant** selected from the group consisting of **lubricants**, for example. As summarized, the invention reads on claims 10-11 and 14.

12. As discussed in a previous Action mailed on 10/16/2008, and reiterated largely as follows, Applicant acknowledges that *Swart et al* (J Analyt Toxicol 18:71-77, 1994) “disclose the (S)-enantiomer of 2-N-propylamino-5-hydroxytetralin” (Applicant’s Specification, Page 2, Paragraph 0012). Specifically, *Swart et al* identified the compound as a metabolite of S(-)-2-N-propyl-N-2-thienylethylamino-5-hydroxytetralin (N-0923) using HPLC with UV detection, combined with atmospheric pressure ionization mass spectrometry (entire document and Page 74, Figure 2, Metabolite 4). More specifically, in being subjected to LC/MS (as evidenced by Page 75, Figure 4), *Swart et al* disclose that the compound was exposed to **nitrogen gas** (Page 74, section entitled ‘D. Mass spectrometric analysis’).

13. As evidenced by *Beane*, nitrogen gas is a lubricant (Page 384, Second Paragraph, “using nitrogen gas as the lubricant”).

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14. As such, the solution encompasses a "pharmaceutical composition comprising (S)-2-N-propylamino-5-hydroxytetralin... and at least one pharmaceutically acceptable carrier or adjuvant" selected from the group consisting of lubricants, for example.

15. Accordingly, instant claims 10-11 and 14 are anticipated.

16. Instant claim 13 is drawn to the composition of claim 10 that is adapted for transdermal, transmucosal or parenteral administration. Applicant is advised that use limitations (i.e., adapted for transdermal, transmucosal or parenteral administration) within product claims do not carry patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, absent evidence to the contrary, it is asserted that the prior art composition can be adapted for transdermal, transmucosal or parenteral administration.

17. Accordingly, instant claim 13 is also rejected.

Claim Objections

18. Claim 12 is objected to as depending from a rejected base claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628